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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
07/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/727,580	SAUVAGEAU ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,12,13,18,20,23,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9,12,13,18,20,23,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment, filed 4/17/2008, in which claims 1-6, 8, 10-11, 14-17, 19, 21-22 and 24-25 were canceled, claims 7, 9, 12-13, 18, 20 and 23 were amended, and claims 26-27 were newly added. Currently, claims 7, 9, 12-13, 18, 20, 23 and 26-27 are pending.

Applicant's arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn. **This action is FINAL.**

Election/Restrictions

Applicant elected Group II with traverse in the reply filed on 6/29/2006. Applicant elected the species HOXB4 with traverse in the reply filed on 10/2/2006.

Currently, claims 7, 9, 12-13, 18, 20, 23 and 26-27 are under consideration.

Response to Arguments - Claim Objections

The objection of claims 8-13 and 19-23 has been withdrawn in view of Applicant's amendment to the claims in the reply filed 4/17/2008.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 9, 18, 20, 23 and 26-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36 and 38 of copending Application No. 10/530,413 (hereinafter the '413 application). This rejection was made in the Office action mailed 10/18/2007 and has been rewritten to address the amendments to the claims.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 7, 9 and 26 are generic to all that is recited in claim 36 of the '413 application. That is, claim 36 of the '413 application fall entirely with the scope of claims 7, 9 and 26 of the instant application or, in other words, instant claims 7, 9 and 26 are anticipated by claim 36 of the '413 application. Claim 36 of the '413 application is narrower in scope than the instant claims in that it requires the use of the product of claim 15 which comprises additional elements relative to the product use by the method of the instant claims. Specifically, the conflicting claim requires the HOXB4 peptide comprising a HIV PTD from a transactivation protein (TAT), and a blocker, which reduces the expression level of at least one gene normally limiting HOX-induced expansion of stem cells. Furthermore, conflicting claim 38 requires the cells to be human or mouse hematopoietic stem cells. Thus, an obvious variant of conflicting

claim 36 is where the cells are human hematopoietic cells. Accordingly, instant claims 18, 20, 23 and 27 are not patentably distinct from the conflicting claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments - Double Patenting

The rejection of claims 8, 10-11, 19 and 21-22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36 and 38 of copending Application No. 10/530,413 is moot in view of Applicant's cancellation of the claims in the reply filed 4/17/2008.

The rejection of claims 12-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36 and 38 of copending Application No. 10/530,413 has been withdrawn in view of Applicant's amendment to the claims to depend from a canceled claim in the reply filed 4/17/2008.

With respect to the rejection of claims 7, 9, 18, 20, 23 and 26-27 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36 and 38 of copending Application No. 10/530,413, Applicant's arguments filed 4/17/2008 have been fully considered but they are not persuasive.

The response notes that Applicant does not wish to address the double patenting rejection at this time, because the instant application is the earlier filed application and may be permitted to issue as a patent if the provisional double patenting rejection is the only rejection present. Because the case is not in condition for allowance at this time, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection, necessitated by the cancellation of claim 11 without amending claims 12 and 13 to depend from a pending claim, in the reply filed 4/17/2008.

Claim 12 is vague and indefinite in that it depends from a canceled claim. The metes and bounds of the term are unclear because the scope of the claim depends on the limitation of the claim from which it depends. Thus, claim 12 is an incomplete claim. It would be remedial to amend the dependency such that the claim further limits a pending claim.

Claim 13 depends from claim 12 and thus is indefinite for the same reason applied to claim 12.

Response to Arguments - 35 USC § 112

The rejection of claims 10, 11, 21 and 22 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment to the claims in the reply filed 4/17/2008.

The rejection of claims 7, 9-13, 18, and 20-22 under 35 U.S.C. 112, first paragraph (written description), has been withdrawn in view of Applicant's amendment to the claims in the reply filed 4/17/2008.

The rejection of claims 7, 9-13, 18, and 20-22 under 35 U.S.C. 112, first paragraph (scope of enablement), has been withdrawn in view of Applicant's amendment to the claims in the reply filed 4/17/2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 9, 18, 20, 23 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Largman et al (US Patent No. 5,837,507, cited on the IDS filed 8/17/2005) in view of Frankel et al (US Patent No. 5,804,604, cited in a prior action; see the entire reference). This rejection was made in the Office action mailed 10/18/2007 and has been extended to new claims 26-27.

Largman et al teach the expression of an exogenous HOX gene, preferably HOXB4, in a stem cell to generate expanded population of pluripotent stem cells *in vitro* or *in vivo* (e.g., Abstract; column 2, lines 35-59; column 8, lines 5-38; column 11, line 53 to column 12, line 50). The preferred stem cell is a hematopoietic stem cell, such as a human hematopoietic stem cell expressing the cell surface marker CD34 (e.g., column 2, lines 48-59). Largman et al teach that it is the expression of the HOXB4 gene (i.e., the HOXB4 protein) that results in the desired function (e.g., column 12, lines 5-37).

Largman et al do not teach the method where the HOXB4 protein is delivered to the stem cell by crossing the cell membrane as a result of the presence of a HIV-TAT protein.

Frankel et al teach the delivery of biologically active proteins to the cytoplasm and nuclei of cells *in vitro* and *in vivo* by the u se of transport polypeptides which comprise HIV tat protein, which are covalently attached to the cargo protein (e.g., Abstract; column 1, lines 20-40; column 2, line 64 to column 4, line 3; column 7, lines 23-38). Frankel specifically teach the delivery of a transcription factor by TAT mediated protein transduction (e.g., column 12, lines 25-40). Further, Frankel et al teach that methods of DNA delivery typically deliver the nucleic acid molecules into only a fraction of the total cell population and tend to damage large numbers of cells (e.g., column 1, lines 54-63). In contrast, the methods of using the tat protein to deliver proteins provide efficient delivery of non-tat proteins that are not inherently capable of entering target cells or nuclei, or are not inherently capable of entering cells at a useful rate (e.g., column 3, lines 6-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of generating expanded populations of stem cells of Largman et al to replace the delivery of HOXB4 protein by delivering a nucleic acid molecule with the delivery of HOXB4 protein by delivering a tat-conjugated protein as taught by Frankel et al because Largman et al teach it is within the ordinary skill in the art to use HOXB4 protein expression to expand populations of stem cells and Frankel et al teach the delivery of proteins to cells *in vitro* and *in vivo*.

One would have been motivated to make such a modification in order to receive the expected benefit of more efficiently delivering the HOXB4 protein to the nucleus of the cells as

taught by Frankel et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Arguments - 35 USC § 103

The rejection of claims 8, 10-11, 19, 21-22 under 35 U.S.C. 103(a) as being unpatentable over Largman et al in view of Frankel et al is moot in view of Applicant's cancellation of the claims in the reply filed 4/17/2008.

The rejection of claims 12-13 under 35 U.S.C. 103(a) as being unpatentable over Largman et al in view of Frankel et al has been withdrawn in view of Applicant's amendment to the claims to depend from a canceled claim in the reply filed 4/17/2008.

With respect to the rejection of claims 7, 9, 18, 20, 23 and 26-27 under 35 U.S.C. 103(a) as being unpatentable over Largman et al in view of Frankel et al, Applicant's arguments filed 4/17/2008 have been fully considered but they are not persuasive.

The response traverses the rejection based upon the failure of others. The response states that Applicant is not aware of reporting a failed attempt to achieve a functional TAT-HOXB4. Further, the response notes that none of the more than 50 laboratories, which received HOXB4 cDNA constructs from the inventors following their paper of 1994, reported success with a non-gene transfer of HOXB4 while the drawbacks of gene transfer were known. This is not found persuasive, because objective evidence of failed attempts has not been provided. There is no objective evidence that demonstrates that those individuals who received the HOXB4 cDNA intended to use the HOXB4 protein for enhancing expansion of a stem cell population for

therapeutic applications or for expressing a protein to be delivered directly to a stem cell. It may have been the intent of the receiving laboratories to merely use the cDNA to express HOXB4 protein in cells for research purposes. The declaration of Dr. Humphries indicates that none of the laboratories that received the samples has reported success in a non-gene transfer delivery using HOXB4; however, there is no evidence that non-gene delivery was attempted by these laboratories. Furthermore, it was known in the art at the time the invention was made that the TAT protein transduction domain (PTD) could be used with a variety of proteins and cell types. Schwarze et al (Science, Vol. 285, pages 1569-1572, September 1999, cited as reference #4 on the IDS filed 8/17/2005) teach that the HIV TAT PTD had been used to transduce over 50 proteins ranging in size from 15 to 120 kD into a wide variety of human and murine cell types *in vitro* (e.g., paragraph bridging pages 1569-1570). Furthermore, Schwarze et al teach that protein transduction by TAT occurs *in vivo* (e.g., Figure 3). It is likely that if one had attempted to use the TAT peptide to transduce a human or murine cell with HOXB4, the attempt would have been successful.

The response asserts that it was not routine experimentation to produce a functional stem cell expansion factor that comprises HOXB4 protein and a NH_2-terminal protein transduction domain (PTD) from a transactivating protein (TAT) and that it was not predictable whether functional Hoxb4 non-gene delivery could be achieved. The declaration of Dr. Humphries notes that the inventors believe they were the first to use the TAT motif to transfer protein into hematopoietic stem cells (HSCs). However, it was known in the art that fusion proteins comprising TAT PTD were capable of introducing proteins into every cell of the blood and hematopoietic stem cells from bone marrow (Nagahara et al. Nature Medicine, Vol. 4, No. 12,

pages 1449-1452, December 1998, cited as reference #3 on the IDS filed 8/17/2005; e.g., paragraph bridging pages 1449-1450). Further, the declaration of Dr. Humphries states that four to six months were necessary to generate the first TAT-HOXB4 protein due to the time needed to overcome hurdles including methods of production, purification and storage, dosage (amount and frequency), *in vitro* conditions, and nature and characterization of starting cells that would respond. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). In the instant case, the prior art contains sufficient guidance for one to make the TAT-HOXB4 protein required for the method. The present specification states, "Using the pTAT-HA plasmid developed by Nagahara et al. (1998), we will subclone a full-length Hoxb4 cDNA in frame and downstream to the His6-TAT-HA tag. The protein will be produced in bacteria and purified exactly as described by Nagahara (1998)." See page 35, lines 7-11. Thus, the making and purification of the TAT-HOXB4 protein appears to have relied upon the specific guidance provided in the art. To apply this known technique to the HOXB4 protein would have been routine in the art at the time the invention was made and would not have required undue experimentation. The time necessary for routine experimentation or optimization does not establish that the invention was unpredictable.

The response asserts that there was a long-felt but unresolved need for the methods of the present invention. The specific need is characterized as the need for hematopoietic stem cell (HSC) transplantation. The declaration of Dr. Roy indicates that patients in need for HSC transplantation include patients with blood cancer, solid tumors, and some non-malignant disorders, such as anemia, thalassemia or sickle cell anemia; however, 50% of patients in need

for HSC transplantation do not find an HLA matched donor (paragraphs 3-5). The declaration notes that typically about 25% o f patients in need of HSC transplantation find a donor amongst HLA matched siblings, and another 25% find a HLA matched unrelated donor (paragraph 5). The declaration characterizes the options available to those individuals lacking an HLA matched donor as the following: (1) transplantation of umbilical cord blood isolated stem cells, (2) transplantation of mismatched grafts, and (3) autologous transfer of mobilized stem cells.

While the cord blood solution may be costly or raise biological concerns, it is a method that satisfies the long-felt need for a source of HSC for transplantation when a HLA matched donor is not found. At paragraph 8, the declaration notes that expanding HSC could allow greater numbers of HSCs to be obtained from fewer cord blood samples. While this may improve the process, the general solution to the problem was satisfied by another before the instant invention. Even if multiple rounds of collections are necessary to collect enough stem cells for an unmatched transplant, it is still a solution that satisfies the long-felt need. At paragraph 8, the declaration notes that expanding HSC could allow for greater numbers of cells to be obtained from unmatched donors. While this may improve the process, the general solution to the problem was satisfied by another before the instant invention. With respect to autologous transfer of mobilized stem cells, the declaration notes that the procedure is repeated until a sufficient amount of progenitor cells is obtained (paragraph 9). Further, the declaration notes that these cells can be collected from cancer patients and can be treated to remove tumor cells (paragraph 11). Thus, a solution to the problem of no allogeneic HLA matched donor is solved by autologous collection and transplantation. While expansion of HSCs could improve the process of autologous transplantation, this solution existed prior to the instant invention.

At paragraphs 12 and 13 of the declaration of Dr. Roy, the use of HSCs for the repair of damaged tissues such as the heart, neurologic tissue and cartilage is discussed. The declaration notes that HSC expansion could improve these processes. Even if the processes are improved by HSC expansion, there is no evidence that HSC expansion by TAT-HOXB4 was required to satisfy a long-felt need.

At paragraph 14, the declaration of Dr. Roy indicates that there is an "urgent need for a method of expanding HSCs" for use in stem cell transplantation. Methods of hematopoietic stem cell expansion for transplantation were known in the art prior to the effective filing date of the present application (See, for example, WO 94/18991; WO 99/07831, and US Patent No. 5,925,567).

In order to overcome the rejection of record, the long-felt need must have been a persistent one that was recognized by those of ordinary skill in the art. It must exist for a long time without a solution. No evidence has been presented that those of ordinary skill in the art were failed after attempting to deliver HOXB4 protein to a stem cell. If the long-felt need is considered to be a lack of HLA matched donors for HSC transplantation or the need to expand HSCs, this need was satisfied by another before the invention by applicant.

The response notes that there are disadvantages to gene delivery. Disadvantages were recognized in the art at the time the invention was made and would have motivated one to use protein delivery rather than nucleic acid delivery. See Schwarze et al (1999) page 1569, paragraph bridging columns, and the paragraph bridging pages 1569-1570.

The response asserts that the declaration of Dr. Roy attests to the commercial success of the present invention. The declaration of Dr. Roy notes that a pre-IND visit was obtained to

request approval of health of Canada to conduct clinical studies with the HOXB4 construct of the present invention. The declaration notes that work is currently underway to satisfy the government requirements for clinical studies. The declarant also notes that he is not aware of any other clinical trial ongoing for methods of expanding HSCs for bone marrow transplantation that demonstrated efficacy in HSC expansion. This is not found persuasive, because the claimed invention is not commercially available. Thus, objective evidence of commercial success has not been provided.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness. For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Response to Amendment – Declaration of Dr. Humphries

The declaration under 37 CFR 1.132 filed 4/17/2008 is insufficient to overcome the rejection of claims 7-13 and 18-23 based upon the Largman et al and Frankel et al references applied under 35 U.S.C. 103(a) as set forth in the last Office action.

It states that others failed when trying to achieve the claimed invention. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. There is no showing that others of ordinary skill in the art were working to directly deliver HOXB4 protein to stem cells. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

The declaration states that the subject matter of the invention is unpredictable and required more than routine experimentation to generate a TAT-HOXB4 protein for use in the claimed invention. This is not found persuasive for the reasons discussed above.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Amendment – Declaration of Dr. Roy

The declaration under 37 CFR 1.132 filed 4/17/2008 is insufficient to overcome the rejection of claims 7-13 and 18-23 based upon the Largman et al and Frankel et al references applied under 35 U.S.C. 103(a) as set forth in the last Office action.

It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. There is no showing that others of ordinary skill in the art were working to directly deliver HOXB4 protein to stem cells. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

The declaration does not provide evidence of commercial success, because the invention is not commercially available.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

/JD/

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Primary Examiner, Art Unit 1636